Mass General Brigham
Health Plan

Nulibry ® (fosdenopterin)
Effective 11/01/2021

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
Nulibry is cyclic pyranopterin monophosphate (cPMP) indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A.

Coverage Guidelines
Authorization may be reviewed for members new to the plan who are currently receiving treatment with Nulibry excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. Documented diagnosis of molybdenum cofactor deficiency type A
2. Documentation of ONE of the following:
    a. Diagnosis of molybdenum cofactor deficiency type A confirmed by genetic testing
    b. In neonates (up to 28 days after birth), diagnosis based on ONE of the following:
        i. Prenatal genetic diagnosis
        ii. Onset of clinical signs and symptoms consistent with molybdenum cofactor deficiency Type A (e.g., seizures, feeding difficulties, high-pitched cries, exaggerated startle reactions, increased/decreased muscle tone) within the first 28 days after birth
        iii. Onset of laboratory signs and symptoms consistent with molybdenum cofactor deficiency Type A (e.g., elevated urinary sulfite and/or S-sulphocysteine, elevated xanthine in urine or blood, or low or absent uric acid in the urine or blood) within the first 28 days after birth

Continuation of Therapy

Reauthorization will be granted if member meets all of the following criteria:

1. Diagnosis of molybdenum cofactor deficiency Type A confirmed by genetic testing
2. Documented therapeutic response as evidenced by ONE of the following:
    a. Improved change in molybdenum cofactor deficiency biomarkers
    b. Improved growth parameters

Limitations

1. Initial approvals will be granted for 3 months
2. Reauthorizations will be granted for 12 months

References

1. Nulibry [package insert]. Boston, MA: Origin Biosciences, Inc.; February 2021.
2. Atwal PS, Scaglia F. Molybdenum cofactor deficiency. Mol Genet Metab. 2016;117(1):1-4.
3. Schwahn BC, Van Spronsen FJ, Belaidi AA, et al. Efficacy and safety of cyclic pyranopterin monophosphate substitution in severe molybdenum cofactor deficiency type A: a prospective cohort study. Lancet. 2015; 386: 1955-1963.
4. ClinicalTrials.gov. Study of ORGN001 (formerly ALXN1101) in neonates with molybdenum cofactor deficiency (MOCD) type A. Available at: https://clinicaltrials.gov/ct2/show/NCT02629393.
5. ClinicalTrials.gov. Safety & efficacy study of ORGN001 (formerly ALXN1101) in pediatric patients with MoCD type A currently treated with rcPMP. Available at: https://clinicaltrials.gov/ct2/show/NCT02047461.

Review History

09/22/2021 – Reviewed and Created for Sept P&T. Effective 11/01/2021.